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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,035	04/17/2001	Weichao G. Chen	PC10866AMGM	8768

7590

02/07/2002

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EXAMINER

HUANG, EVELYN MEI

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 02/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/836,035

Applicant(s)

CHEN ET AL.

Examiner

Evelyn Huang

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1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-29 and 31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 1-29, 31 are pending. Claim 30 has been canceled according to the amendment filed on 11-16-2001.

Claim Rejections - 35 USC § 102

2. The 102(a) rejection for claim 30 over Hamanaka is rendered moot by the cancellation of the claim.

Claim Rejections - 35 USC § 103

3. The 103(a) rejection for claims 1-29, 31 over Hamanaka is maintained for reasons of record.

The declaration under 37 CFR 1.132 filed on 11-16-2001 has been fully considered but is insufficient to overcome the rejection for the following reasons. Firstly, the measurement of the plasma half-life and the advantageous longer plasma half-life of the instant quinolone compound are not described in the specification. Secondly, the result is not unexpected in view of the disclosure that administration of the 5[-cyclopropyl-1-(quinolin-5-yl)-1-H-pyrazole-4-carbonyl]-guanidine (compound A) lead to the instant 5[-cyclopropyl-1-(quinolon-5-yl)-1-H-pyrazole-4-carbonyl]-guanidine (compound B) in vivo (admitted by the applicant in claim 30). Compound A is therefore a prodrug of compound B (claim 1, proviso) and one of ordinary skill would expect the precursor compound to have a shorter plasma half-life because it is being metabolized. Since unexpected results have not been established, the instant remains obvious over Hamanaka.

4. The 103(a) rejection for claims 1-29, 31 over Hamanaka in view of Munson and Beedham is maintained for reasons of record.

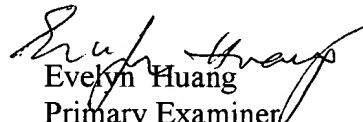
Applicant argues that Munson does not specifically teaches the hydroxylation of the quinoline compound to arrive at the instant quinolone compound. Indeed Munson only generically teaches the hydroxylation reaction as one of the possible metabolic pathways in the body, but this text-book teaching serves to demonstrate that it is a well known metabolism.

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Furthermore, Beedham specifically teaches the oxidation of quinoline to 2-quinolone by an oxidase in the liver. Beedham's compound is not identical to but is similar to the instant quinolinyl compound, and one of ordinary skill in the art would expect the same oxidation reaction occurs in the instant quinolinyl compound. The Declaration fails to render the instant unobvious for reasons set forth in the preceding paragraph. In the absence of unexpected results, the instant remains obvious over the prior art of record.

Double Patenting

5. The provisional obviousness-type double patenting rejection over 09/367731 is maintained for reasons set forth in paragraph 3 above.
6. The provisional obviousness-type double patenting rejection over 09/367731 in view of Munson and Beedham is maintained for reasons set forth in paragraph 4 above.
7. The provisional obviousness-type double patenting rejection over 09/657254 is withdrawn upon reconsideration in view of applicant's remarks.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Evelyn Huang
Primary Examiner
Art Unit 1625

January 30, 2002